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To determine the efficacy of lycopene as compared to multivitamin preparation in the treatment of Oral Submucous Fibrosis

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Abstract
Objectives: The study was done to assess the efficacy of lycopene in the treatment of Oral Sub mucous fibrosis (OSMF) among patients visiting Dental College in Garhwa, Jharkhand.
Materials and Methods: Thirty OSMF patients were divided into two groups A and B, Group A, patients received combination of lycopene (16 mg) in divided doses. Group B, patients received combination of multivitamin preparation. Treatment outcome was evaluated on the basis of improvement in symptom score.
Results: The result showed that OSMF patients receiving lycopene have more improvement in burning sensation and with some improvement in mouth opening.
Conclusion: The results of the study clearly indicate that efficacy of lycopene is higher compared to multivitamin preparation.

Keywords: OSMF, lycopene, multivitamin, burning, preparation

1. Introduction

Pindborg and Sirsat defined oral submucous fibrosis (OSMF) as an insidious chronic fibrotic disease that involves the oral mucosa and occasionally the pharynx and upper third of the esophagus. OSMF is characterized by a juxtaepithelial inflammatory reaction followed by fibroelastic changes in the submucosa and epithelial atrophy. This leads to stiffness of the oral mucosa and causes trismus and an inability to eat [1]. Various factors such as chewing habits (areca nut, pan masala), genetics, autoimmunity, nutritional deficiencies, and environment have been considered in the etiology of OSMF. A number of chewing substrates, amongst which areca nut appears to be the most prominent, have been associated with OSMF [2].

People visiting outpatients department, VDCH Dental college Garhwa, Jharkhand,commonly used areca nut, pan masala, and tobacco products like mawa, betel quid, guthka, and khaini.

Lycopene is an important intermediary product in the biosynthesis of many carotenoids, which include β‑carotene, responsible for yellow, orange, or red pigmentation, photosynthesis, and photo‑protection. Like all carotenoids, lycopene is a polyunsaturated hydrocarbon (an unsubstituted alkene) [3]. The ideal intake of lycopene is currently indefinite; however, one study suggested that at least 5-10 g of fat in a meal is required for lycopene absorption and 6 mg/day of lycopene is beneficial for prostate cancer prevention. Many epidemiological studies implicated lycopene in the prevention of cardiovascular disease and cancer [4].

The main aim and objective of this study was to evaluate the clinical response of OSMF to the antioxidant lycopene.

2. Materials and Methods

This study was conducted in department of oral medicine and radiology, Vananchal dental college, Garhwa. Total 30 patients diagnosed with OSMF case were divided equally in to treatment groups A & B.

Subjects aged 15 years and above were included in the study. Subjects with any systemic diseases and malignancy were excluded from the study. An ethical clearance was obtained from ethical committee of dental college.

A predesigned proforma was used to record the data. The clinical diagnosis of OSMF was made when subjects showed characteristic feature of OSMF, blanching and stiffness of the oral mucosa, presences of fibrous bands in buccal mucosa, and difficulty in mouth opening [5].

This study, the clinical parameters that were evaluated are as follows

1. Symptomatic relief in the form of absence of burning sensation in the mouth and spontaneous healing of the ulcers when present.
2. Changes in the color of the oral mucosa
3. Improvement in mouth opening

Patients in group A received lycopene(lycored) Capsule containing 100% natural lycopene with zinc, selenium and added phytonutrients, which was given 16 mg in two divided doses and those in group B received multivitamin preparation (Zincovit, Apex laboratories limited) twice daily for a period of 4 month. Treatment responses are assessed clinically by bimonthally evaluation with clinical examination.

The responses were classified as follow [5, 6]

1. **Complete**
   - When the color of the mucosa turned from blanched white to normal pink
   - When there was a definite improvement in the burning sensation,

- When there was an increase in the mouth opening. Ranged from 2 to 3 mm

2. **Partial:** When there was a partial improvement in the above said signs and symptoms and mouth opening was increased by 0.4 to 1 mm.
3. **Stable:** When there was no response and no improvement.
4. **Disease progression:** When there was an increase in the signs and symptoms in spite of having undergone the treatment

Armamentariums used were measuring caliper for mouth opening, mouth mirror, explorer, kidney tray instrument, disposable surgical latex gloves, mask and questionnaires. The statistical analysis was done by SPSS software, version 11.5.

3. Results

Table 1: Patients of group A (lycopene) having OSMF: Pretreatment and post treatment

S. No	Age/sex	Mouth opening(mm)		Improvement(mm)	Burning sensation	
		Prior to treatment	Post treatment		Prior to treatment	Post treatment
1	20/M	35	37	2	mild	Subsided
2	25/M	30	34	4	mild	Reduced
3	35/M	28	30	2	moderate	Subsided
4	40/M	30	34	4	severe	Subsided
5	33/M	23	26	3	moderate	Reduced
6	34/F	22	24	2	severe	Subsided
7	27/M	30	34	4	mild	Reduced
8	47/F	32	34	2	moderate	Subsided
9	41/M	25	26	1	moderate	Reduced
10	22/F	31	32	1	severe	Subsided
11	50/M	34	37	3	mild	Subsided
12	26/M	34	35	2	severe	Reduced
13	34/M	23	24	1	moderate	Subsided
14	41/M	25	26	1	severe	Subsided
15	29/M	17	21	4	mild	Subsided

Table 2: Patients of group B having OSMF: Pretreatment and post treatment

S. No	Age/sex	Mouth opening(mm)		Improvement(mm)	Burning sensation	
		Prior to treatment	Post treatment		Prior to treatment	Post treatment
1	23/M	35	37	2	mild	Subsided
2	26/M	30	30	0	mild	Reduced
3	30/M	28	29	1	moderate	Subsided
4	40/M	30	32	2	severe	Reduced
5	36/M	23	23	0	moderate	Reduced
6	31/M	22	24	2	severe	Subsided
7	27/M	30	30	0	mild	Reduced
8	41/F	32	33	1	moderate	Reduced
9	30/M	25	26	1	moderate	Reduced
10	32/F	31	32	1	severe	Reduced
11	40/M	34	34	1	mild	Subsided
12	26/M	34	36	2	severe	Reduced
13	44/M	23	23	0	moderate	Reduced
14	31/F	25	26	1	severe	Reduced
15	24/M	17	18	1	mild	Reduced

Table 3: Response data

Response	Number of Patients		Percentage	
	Group A	Group B	Group A	Group B
Number evaluable	15	15	-	-
Complete response	10	5	67%	33%
Partial response	5	6	33%	40%
Progression	-	4	0 %	27%

Table 1 shows distribution of patients in group A which were treated with lycopene. Out of all patients there were 12 male, and 3 female. The patients who treated with lycopene, 10 patients showed complete response towards the treatment and 5 patients showed partial responses.

Table 2 shows distribution of patients in group B which were treated with Multivitamin. Out of all patients there were 12 male, and 3 female. The patients who treated with Multivitamin, 4 patients showed complete response towards the treatment and 11 patients showed partial responses.

Table 3 shows the response data of patients in group A and B which treated with lycopene and multivitamin. Patients who treated with lycopene, showed 67% complete response and 33% showed partial response compared with patients in group B which showed 33% complete, 40% partial and 27 % stable response.

4. Discussion

Oral submucous fibrosis (OSMF) is a chronic, premalignant condition of the oral mucosa which was first described by Schwartz 1952 [7]. Worldwide, estimates of OSMF shows a confinement to Indians and Southeast Asians, with overall prevalence rate in India to be about 0.2% to 0.5 % and prevalence by gender varying from 0.2-2.3% in males and 1.2-4.57% in females [8].

The condition is well recognized for its malignant potential rate of 7.6% and is particularly associated with use of areca nut in various forms with significant duration and frequency of chewing habits. The alkaloids and flavonoids (arecoline, arecaidine, tannins and catechins) stimulate collagen synthesis and proliferation of fibroblasts and can act both as a chemical and physical irritant to oral mucosa [9].

The present study shows improvement in mouth opening, tounge protrusion & burning sensation in patients who were treated with lycopene compared with patients who receiving multivitamin. The patients treated with lycopene showed 67% complete response and 33% patients showed partial response.

OSMF is an immunodeficient, incurable disease. No treatment modality either surgical, medical and physiotherapy has been completely successful in eliminating this disease. In view of the strong relationship between oral cancer and precancerous lesion and condition, chemo prevention is said feasible and practicable easily. A simple and safe modality of treatment as describe in this study, along with proper habit restriction is required in OSMF to ensure that the progression of the disease is retarded and the maximum relief is obtained by the patients [10, 11].

In the biosynthesis of many carotenoids, lycopene is an important intermediate. Lycopene has been seen to have many anti-carcinogenic and antioxidant properties. It also plays a role in the improvement of precancerous lesions. Studies also suggest that as lycopene inhibits hepatic fibrosis in rats and human fibroblast activity *in vitro*, it appears to be a promising agent in the management of OSMF. So far, studies on the management of OSMF using lycopene are only few [12].

Restriction of mouth opening is a major disability associated with OSMF. An improvement of a few millimeters has been reported. In our study a significant improvement was seen in Group A Patients. Kumar *et al*. also conducted a similar study in 2007, on efficacy of lycopene in the management of OSMF. They reported that the mouth opening was increased by 3.4 mm in patients receiving 16 mg of lycopene and 4.6 mm in patients receiving 16 mg of lycopene along with biweekly Intralesional steroid injections [13].

5. Conclusion

A best clinical response was seen in study groups in this study when compared with lycopene and multivitamin. Lycopene was seen to be a safe efficacious, reliable drug in the treatment of OSMF. In compare to other treatment modalities for OSMF, it offers a noninvasive option that significant improvements in the symptoms as well as objective sign of the condition.

This is a short study with less number of OSMF cases with small sample size. A long term study with a larger sample size with all above variables being taken into consideration would necessary to get a clear picture about the utility of this drugs.

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